



U.S. ENVIRONMENTAL PROTECTION AGENCY
 Office of Pesticide Programs
 Biopesticides and Pollution Prevention Division (7511P)
 1200 Pennsylvania Ave., N.W.
 Washington, D.C. 20460

EPA Reg. Number:

91283-13

Date of Issuance:

12/15/2022

NOTICE OF PESTICIDE:

Registration
 Reregistration
 (under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Amoéba EP #1

Name and Address of Registrant (include ZIP Code):

Amoéba SA
 38 Avenue des Frères Montgolfier
 F-69680 CHASSIEU – France

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of your product when EPA requires all registrants of similar products to submit such data.

Signature of Approving Official:

Alexandra Boukedes
 Digitally signed by
 ALEXANDRA BOUKEDES
 Date: 2022.12.15 16:54:43
 -06'00'

Alexandra Boukedes, Product Manager 92
 Microbial Pesticides Branch
 Biopesticides and Pollution Prevention Division (7511M)
 Office of Pesticide Programs

Date:

12/15/2022

2. Make the following labeling change before you release this product for shipment:
 - Revise the EPA Registration Number to read, “EPA Reg. No. 91283-13.”
3. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to EPA’s Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statement of Formula (CSF)

- Basic CSF dated 12/15/2022

If you have any questions, please contact Jennifer Odom-Douglas via email at odomdouglas.jennifer@epa.gov.

Sincerely,


Digitally signed by
ALEXANDRA
BOUKEDES
Date: 2022.12.15
16:55:20 -06'00'

Alexandra Boukedes, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511M)
Office of Pesticide Programs

Enclosure

[Text in brackets [] and bulleted language at end of document indicates optional language and may not appear on final printed label]

[Note: Units of measure are presented in both US and metric units in this label and these units will be optional on final printed label]

Amoéba EP #1

[Alternate Brand Name: Biomeba 3%]

For control of microbial slime (bioslime), microbially induced corrosion and general non-public health microbial flora in closed cooling water systems.

ACTIVE INGREDIENT:

*Willaertia Magna C2c Maky** 0.10%

OTHER INGREDIENTS: 99.90%

TOTAL: 100.00%

*contains a minimum of 5.7×10^8 *Willaertia Magna C2c Maky* cells/gallon of product [US units]

*contains a minimum of 1.5×10^8 *Willaertia Magna C2c Maky* cells/liter of product [metric units]

KEEP OUT OF REACH OF CHILDREN CAUTION

| FIRST AID | |
|---|---|
| If swallowed | <ul style="list-style-type: none">• Call a poison control center or doctor immediately for treatment advice.• Have person sip a glass of water if able to swallow.• Do not induce vomiting unless told to do so by a poison control center or doctor.• Do not give anything by mouth to an unconscious person. |
| If on skin or clothing | <ul style="list-style-type: none">• Take off contaminated clothing.• Rinse skin immediately with plenty of water for 15 - 20 minutes.• Call a poison control center or doctor for treatment advice. |
| If inhaled | <ul style="list-style-type: none">• Move person to fresh air.• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.• Call a poison control center or doctor for further treatment advice. |
| HOTLINE NUMBER: Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies, call the poison control center at 1-800-222-1222. For general information on this product, call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Standard Time, or at http://npic.orst.edu . | |

[See [Side] [or] [Back] [or] [Other] Panel[s] for Additional Precautionary Statements]

Manufactured [by] [for]:

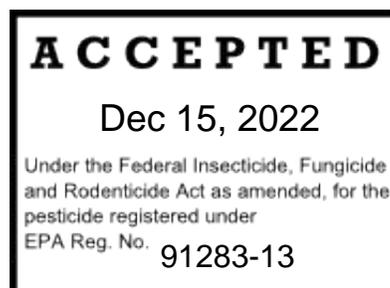
Amoéba SA

38 avenue des Frères Montgolfier

F-69680 CHASSIEU – France

EPA Reg. No 91283-RG

EPA Est. No. 91283-FRA-001



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Net contents: [5 liters] [169 fl. oz] [10 liters] [338 fl. oz] [20 liters] [676 fl. oz]

Lot No. XXX [will appear on label or container]

Expiration Date: XXXX [will appear on label or container] [will be 14 days from date of manufacture]

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Harmful if swallowed, absorbed through skin, or inhaled. Avoid breathing spray mist. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Applicators and other handlers must wear:

- long-sleeved shirt,
- long pants,
- shoes,
- socks, and
- waterproof or chemical-resistant gloves.

Mixer/loaders and applicators must wear a NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

[See [Side] [or] [Back] [or] [Other] Panel[s] for specific instructions]

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

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RESTRICTIONS

Do not use in open or semi-open systems. Closed cooling water systems are defined as a closed-loop recirculating cooling system that does not release treated water to the environment.

As the active ingredient is a living organism, the following restrictions apply:

Do not use Amoéba EP #1 in conjunction with any disinfection program.

Amoéba EP #1 is compatible with some chemical products, such as anti-scale or anti-corrosion products. Contamination with certain chemicals could result in lack of efficacy. Contact your local water treatment company representative for more information.

APPLICATION INSTRUCTIONS

Williaertia Magna C2c Maky, the active ingredient in Amoéba EP #1, is a free-living amoeba acting as a microbial pest control agent. Amoéba EP #1 is intended for the treatment/control of microbial slime (bioslime), microbially induced corrosion and general non-public health microbial flora in closed cooling water systems. For use in closed systems containing raw, cooling, or process water. For use only in closed water systems with defined inlets [and] [or] outlets. The frequency of addition of Amoéba EP #1 depends on many factors, such as history of the microbial contamination of the cooling tower, source of make-up water, cleanliness of the system. To optimize use of Amoéba EP #1, follow the instructions below:

Keep Amoéba EP #1 under continuous stirring (80 – 120 rpm) from receipt until end of injection in order to ensure uniform dispensing into the water system.

Amoéba EP #1 may be fed on a "shock" (batch) basis or on a continuous basis.

For continuous feed treatment, Amoéba EP #1 must be used with a dedicated injection and stirring device that meets Amoéba EP #1 label and dose requirements [for example, the Amoéba BIOMEBOX dosing control unit]). Follow manufacturer's directions for equipment use.

Directly inject Amoéba EP #1 into the water circuit. Adapt the quantity of injected Amoéba EP #1 to the flow rate of processing make-up water or water system volume. Routine treatment is determined in collaboration with your local water treatment company representative. It mainly depends on the cleanliness and age of the system.

COOLING AND PROCESS WATER SYSTEMS - [cooling towers] *When used as directed, Amoéba EP #1 effectively controls non-public health bacteria and slime. Add Amoéba EP#1 to the system directly. Add Amoéba EP #1 at a point in the system where uniform mixing and even distribution will occur, such as the cooling tower basin sump or cooling tower make-up water.*

The tables below (US units and SI units) identify the volume of Amoéba EP #1 to be injected per make-up water volume [continuous feed treatment or shock treatment] to reach target concentration in water system:

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| US units | <i>Willaertia magna</i> C2c Maky target concentration in water [continuous feed treatment or shock treatment] | Volume of Amoéba EP #1 per 1000 gallons water system |
|------------------------------------|---|--|
| Lowest recommended concentration | 7.6 x 10 ³ cells per gallon | 1.7 fl. oz. |
| Standard treatment | 7.6 x 10 ⁴ cells per gallon | 17 fl. oz. |
| Highest authorized concentration * | 3.8 x 10 ⁵ cells per gallon | 6.40 gal. |

* Under the following conditions, the standard treatment can be increased up to the highest authorized concentration, in collaboration with an Amoéba representative:

- In case of upward trend in non-public health bacteria and/or slime.
- At the beginning of the treatment or after cleaning.

| SI units | <i>Willaertia magna</i> C2c Maky target concentration in water [continuous feed treatment or shock treatment] | Volume of Amoéba EP #1 per m ³ water system |
|------------------------------------|---|--|
| Lowest recommended concentration | 2.0 x 10 ⁶ cells / m ³ | 13 mL |
| Standard treatment | 2.0 x 10 ⁷ cells / m ³ | 133 mL |
| Highest authorized concentration * | 1.0 x 10 ⁹ cells / m ³ | 6.7 L |

* Under the following conditions, the standard treatment can be increased up to the highest authorized concentration, in collaboration with an Amoéba representative:

- In case of upward trend in non-public health bacteria and/or slime.
- At the beginning of the treatment or after cleaning.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in original container at room temperature. Do not store near food or feed commodities. Keep container tightly closed when not in use. This product is stable for 14 days. Users must use product prior to the expiration date shown on the packaging to ensure maximum efficacy.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

CONTAINER HANDLING:

Non-refillable container: Do not reuse or refill this container. Triple rinse as follows: Empty the remaining contents into application equipment and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Offer for recycling or reconditioning and dispose of in trash or in a sanitary landfill or by incineration.

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[NOTICE TO USER] [WARRANTY]:

This product is to be used only in accordance with the directions on this label. To the extent consistent with applicable law, the user assumes the risk to persons or property that arises from any such use of this product. By using this product, user or buyer accepts the following conditions and disclaimers.

The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product, such as the manner of use or application, all of which are beyond the control of Amoéba. All such risks shall be assumed by the user or buyer.

To the extent consistent with applicable law, Amoéba makes no other warranties, express or implied, of merchantability or of fitness for a particular purpose or otherwise, that extend beyond the statements made on this label. To the extent consistent with applicable law, Amoéba disclaims any liability whatsoever for special, incidental, or consequential damages resulting from the use or handling of this product.

OPTIONAL LABEL LANGUAGE

- Reduce[s] slime.
- Reduce[s] bioslime.
- Reduce[s] microbial slime.
- Easy to use.
- Scent free.
- Controls general non-public health bacterial growth.
- Controls slime forming non-public health bacteria.
- Controls bioslime forming non-public health bacteria
- [Amoéba EP #1] is a concentrate formulation designed for use in commercial, institutional, and industrial operations.
- [Amoéba EP #1] controls the growth of slime-forming non-public health bacteria.
- Use [Amoéba EP #1] in closed cooling water systems.
- For use in commercial, institutional and industrial closed water systems.
- Reduce non-public health bacterial-induced corrosion.
- For use in [closed system] [containerized ponds].
- For use in industrial scrubbing systems and air washers (closed systems only).
- For use in recirculating cooling and process water systems (closed systems only).
- For use as a slimicide.
- For use in closed heat transfer systems.
- Controls slime deposits in pumps, pipe work, heat exchangers, and filters associated with closed cooling water systems.
- Active ingredient *Williaertia magna* C2c Maky is a [free-living] amoeba.

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- Compatible with commonly used anti-scaling and anti-corrosion products.
- Effective in the water phase and on slime[s].
- Quick connect system.
- Contributes to sustainable development.
- Control of biological growth in closed circuits.
- Reduced need for blow-down, saving water and cost.
- Easy to handle, recyclable package.
- Reduce storage space by up to 100%.
- Large operating conditions: Temperature between 53.6°F and 125.6°F; pH from 5 to 10.
- Quick connect system reduces handling time.
- Multiple injection strategies: continuous or shock doses.
- Injection by dosing pump.
- A [live] biocontrol organism.
- Amoeba is a biocontrol organism and actively [feeds][grazes] on slime [containing][non-public health bacteria].
- Isolated from historic thermal baths in the Alps.
- A [treatment][of][for] [slime-forming non-public health bacteria] [non-public health bacterial-induced corrosion].
- Uses a living [organism][amoeba][biocontrol organism] to [depress][suppress][control] [populations of] [non-public health bacteria][slime][slime-causing non-public health bacteria].
- A biological control: Uses a beneficial species of amoeba to control undesirable [non-public health bacteria][slime]
- Uses a [biocontrol][biocontrol organism][amoeba] to establish a long-term balance, reducing slime.
- Reduces slime with a biocontrol organism.
- Consumes slime and non-public health bacteria.
- [Biocontrol][biological control] isn't just for the farm.
- A biological control [method][product][organism] for [slime-forming non-public health bacteria][non-public health bacteria].
- Uses a living [organism] [beneficial][amoeba] to [graze on][suppress] [non-public health bacterial populations][slime].
- Amoeba [grazes on][seeks out][feeds on] slime and slime-forming non-public health bacteria.